Pliva v. Mensing

131 S.Ct. 2567 (2011)

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Region: Americas
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Court: Supreme Court
Health Topics: Health information, Health systems and financing, Medicines

Facts

Metoclopramide is a drug commonly used to treat digestive tract problems such as diabetic gastroparesis and gastroesophageal reflux disorder. In 1980, the Food and Drug Administration (FDA) first approved metoclopramide tablets under the brand name Reglan. Generic manufacturers also began producing metoclopramide five years later. Over its usage history, evidence accumulated that long-term metoclopramide use could cause tardive dyskinesia, a severe neurological disorder. Warning labels had therefore been strengthened and clarified on occasion for prescription brand-name Reglan.

Respondents were prescribed Reglan and received generic metoclopramide. The generic versions, however, did not come with the same explicit warnings found on the brand-name, Reglan. Respondents claimed that they continued use and developed tardive dyskinesia as a result.

Respondents sued the manufacturers of the variety of metoclopramide they used (Manufacturers). The Respondents alleged that â€œlong-term metoclopramide use caused [their] tardive dyskinesia and that the Manufacturers were liable under state tort lawâ€¦for failing to provide adequate warning labelsâ€•â€”as none of the Manufacturers had changed their labels to adequately warn of the danger. The Manufacturers argued â€œFDA regulations required them to use the same safety and efficacy labeling as their brand-name counterparts,â€• making it impossible to have simultaneously complied with both federal law and state tort law duty that required them to use a different label. The â€œCourts of Appeals for the Fifth and Eighth Circuits rejected the Manufacturersâ€™ arguments and held thatâ€• the claims were not pre-empted. The suits were consolidated into th present one for the Supreme Courtâ€™s consideration.

Decision and Reasoning

The Court first examined whether state tort law conflicted with FDA regulations in this case in order to determine whether pre-emption was an issue in the case. The Court determined that it did in fact conflict. It stated that state tort law required a drug manufacturer that was or should have been aware of its productâ€™s danger to label that product in a way that rendered it reasonably safe. However, the FDA interpreted its regulations to require that the warning labels of a brand-name drug and its generic copy must always be the sameâ€”creating an ongoing federal duty of â€œsameness.â€• Respondents contended that federal law provided several avenues through which the Manufacturers could have altered their metoclopramide labels in time to prevent the injuries after initial FDA approval. However, the court considered it impossible for the Manufacturers to do so.Â Â

The Court then examined whether the state laws were pre-empted by the Supremacy Clause. The Court held that the Respondentâ€™s claims were pre-empted by federal law. As stated, federal law would permit the Manufacturers to comply with the state labelling requirements only if the FDA and the brand-name manufacturer changed the brand-name label to do so. Yet although the Manufacturers did not even try to start a process that might ultimately have allowed them to use a safer label, the question for impossibility was â€œwhether the private party could independently do under federal law what state law require[d] of it.â€• Accepting Respondentsâ€™ argument that the Manufacturers had to at least try for the change would â€œrender conflict pre-emption largely meaningless because it would make most conflicts between state and federal law illusory,â€• and leave the Supremacy Clause with little force. The Supremacy Clause made federal law â€œthe supreme Law of the Landâ€• even absent an express statement by Congress. The text â€œplainly contemplate[d] conflict pre-emption by describing federal law as effectively repealing contrary state law.â€•

The Court then examined whether the decision ended all responsibility for generic drug manufacturers to

independently try to update their labels for safety purposes. â€œ21 U. S. C. Â§352(f)(2)â€¦ provides that a drug is â€˜misbrandedÂ . . . [u]nless its labeling bears . . . adequate warnings against . . . unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users.â€™â€• Under FDA rules, â€œthe Manufacturers could have proposedâ€”indeed, were required to proposeâ€ warning labels to the agency if they believed such warnings were needed.â€• If the FDA agreed it was necessary, â€œit would have worked with the brand-name manufacturer to create a new label for both the brand-name and generic drug.â€• The â€œManufacturers and the FDA disagree over whether this alleged duty to request a strengthened label actually existed.â€• The Court declined to address the existence of this duty because even if it did exist there would still have ultimately been the holding of pre-emption.

Decision Excerpts

â€œWhat is in dispute is whether, and to what extent, generic manufacturers may change their labels after initial FDA approval. Mensing and Demahy contend that federal law provided several avenues through which the Manufacturers could have altered their metoclopramide labels in time to prevent the injuries here. The FDA, however, tells us that it interprets its regulations to require that the warning labels of a brand-name drug and its generic copy must always be the sameâ€”thus, generic drug manufacturers have an ongoing federal duty of â€˜sameness.â€™ U. S. Brief 16; see also 57 Fed. Reg. 17961 (1992) (â€˜[T]he [generic drugâ€™s] labeling must b same as the listed drug productâ€™s labeling because the listed drug product is the basis for [generic drug] approvalâ€™).â€• 131 S.Ct., pp. 2574 â€“ 2575.

â€œAccording to the FDA, these requirements apply to generic drugs. As it explains, a â€˜â€˜central premise of fede drug regulation is that the manufacturer bears responsibility for the content of its label at all times.â€™â€™ U. S. Bri 12â€“13 (quoting Wyeth, 555 U. S., at 570â€“571). The FDA reconciles this duty to have adequate and accuratelabeling with the duty of sameness in the following way: Generic drug manufacturers that become aware of safety problems must ask the agency to work toward strengthening the label that applies to both the generic and brandÂ-name equivalent drug. U. S. Brief 20.â€• 131 S.Ct., p. 2576.

â€œThis raises the novel question whether conflict preemption should take into account these possible actions by the FDA and the brand-name manufacturer. Here, what federal law permitted the Manufacturers to do could have changed, even absent a change in the law itself, depending on the actions of the FDA and the brand-name manufacturer. Federal law does not dictate the text of each generic drugâ€™s label, but rather ties those labels to theirÂ brand-name counterparts. Thus, federal law would permit the Manufacturers to comply with the state labeling requirements if, and only if, the FDA and the brand-name manufacturer changed the brand-name label to do so.â€• 131 S.Ct., p. 2578.